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George W. Johnston
Hoffman-La Roche Inc.
Patent Law Department
340 Kingsland Street
Nutley, New Jersey 07110

In Re: Patent Term Extension
Application for
U.S. Patent No. 6,083,953

NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No. 6,083,953, which claims the human drug product VALCYTE® (valganciclovir HCl), a method of its use and a pharmaceutical composition comprising VALCYTE® (valganciclovir HCl), is eligible for patent term extension under 35 U.S.C. § 156. The period of extension has been determined to be 244 days.

A single request for reconsideration of this final determination as to the length of extension of the term of the patent may be made if filed within one month of the date of this notice. Extensions of time under 37 CFR § 1.136(a) are not applicable to this time period. In the absence of such request for reconsideration, the Director will issue a certificate of extension, under seal, for a period of 244 days.

The period of extension, if calculated using the Food and Drug Administration determination of the length of the regulatory review period published in the Federal Register of February 19, 2003, (68 Fed. Reg. 8027), would be 271 days. Under 35 U.S.C. § 156(c):

$$\begin{aligned}\text{Period of Extension} &= \frac{1}{2}(\text{Testing Phase}) + \text{Approval Phase} \\ &= \frac{1}{2}(1,919 \text{ days} - 1,741 \text{ days}) + 182 \text{ days} \\ &= 271 \text{ days (0.7 years)}\end{aligned}$$

Since the regulatory review period began June 30, 1995, before the patent issued (July 4, 2000), only that portion of the regulatory review period occurring after the date the patent issued has been considered in the above determination of the length of the extension period 35 U.S.C. § 156(c). (From June 30, 1995, to and including, July 4, 2000, is 1,741 days; this period is subtracted for the number of days occurring in the testing phase according to the FDA determination of the length of the regulatory review period.) No determination of a lack of due diligence under 35 U.S.C. § 156(c)(1) was made.

However, the 14 year exception of 35 U.S.C. § 156(c)(3) operates to limit the term of the extension in the present situation because it provides that the period remaining in the term of the patent measured from the date of approval of the approved product plus any patent term extension cannot exceed fourteen years. The period of extension calculated above, 271 days, would extend the patent from July 28, 2014 to April 25, 2015, which is beyond the 14-year limit (the approval date is March 29, 2001, thus the 14 year limit is March 29, 2015). The period of extension is thus limited to 244 days, by operation of 35 U.S.C. § 156(c)(3). Accordingly, the period of extension is the number of days to extend the term of the patent from its original expiration date, July 28, 2014, to and including, March 29, 2015, or 244 days.

The limitations of 35 U.S.C. 156(g)(6) do not operate to further reduce the period of extension determined above.

Upon issuance of the certificate of extension, the following information will be published in the

Official Gazette:

U.S. Patent No.: 6,083,953
Granted: July 4, 2000
Original Expiration Date¹: July 28, 2014
Applicant: John Joseph Nestor, et al.
Owner of Record: Roche Palo Alto LLC
Title: 2- (2-AMINO-1,6-DIHYDRO-6-OXO-PURIN-9-YL) METHOXY-1,3- PROPANEDIOL DERIVATIVE
Product Trade Name: VALCYTE® (valganciclovir HCl)
Term Extended: 244 days
Expiration Date of Extension: March 29, 2015

Any correspondence with respect to this matter should be addressed as follows:

By mail: Mail Stop Patent Ext. By FAX: (571) 273-7755
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450.

Telephone inquiries related to this determination should be directed to Mary C. Till at (571) 272-7755.

Kery A. Fries
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Senior Legal Advisor
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Office of the Deputy Assistant Commissioner
for Patent Policy and Projects

cc: Office of Regulatory Policy
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RE: VALCYTE® (valganciclovir HCl)
FDA Docket No.: 01E-0403

Attention: Claudia Grillo

¹Subject to the provisions of 35 U.S.C. § 41(b).